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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/946,710	10/08/97	BROD S	D5716CIP4

IM62/0825

SARAH J BRASHEARS
MCGREGOR AND ADLER
8011 CANDLE LANE
HOUSTON TX 77071

EXAMINER	
SAYALA,C	
ART UNIT	**PAPER NUMBER**
1761	18

DATE MAILED: 08/25/99

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 18

Serial Number: 08/946710
Filing Date: 10/8/97
Appellant(s): Staley A. Brod

Benjamin Aaron Adler

For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 6/23/99.

(1) Real Party in Interest.

A statement identifying the real party is contained in the brief.

(2) Related Appeals and Interferences.

A statement identifying the related appeals and interferences

which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of claims.

The statement of the status of claims contained in the brief is correct. Claims pending are 1-18.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of invention.

The summary of invention contained in the brief is correct.

(6) Issues.

The appellant's statement of the issues in the brief is correct.

(7) Grouping of claims.

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because although appellant has considered claims 1-18 to lie in four embodiments, claims 1-18 are not separately patentable as grouped since claims 1-7 include in their breadth each of the other

embodiments such that if claims 1-7 stand or fall so should claims 8-20. Indeed, the same may be said of claims 8-11, 12-15 and 16-18 wherein "decreasing the incidence of insulin-dependent diabetes mellitus" is inter-related to and concomitant with "reducing blood glucose levels" and "decreasing the onset of insulin-dependent diabetes mellitus in at-risk populations".

(8) Claims appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of record.

US 5019382	Cummins, Jr.	5/1991
US 5624895	Sobel	4/1997
WO 9420122	Sobel	9/1994
Shibutani et al.	Iyakuhin Kenkyu, Vol. 18(4), pages 571-582, 1987	
Gross et al.	Deutsche Medizinische Wochenschrift, vol. 111(36), pages 1351-5, 1986	
Giron et al.	J. Interferon Res., Vol. 8(6), pages 745-53, 1988.	

(10) New prior art.

No new prior art has been applied in this examiner's answer.

(11) Grounds of rejection.

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1. The following is a quotation of the appropriate

paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

2. Claims 1-4, 6 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cummins, Jr. (U.S. Patent 5019382).

See col. 4, lines 19-36, col. 5, lines 50-55, col. 6, lines 12-26, col. 13, and the claims. Such disclosure meets the claims.

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claim 5 is rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382). The disclosure is the same as above as discussed for claim 1. The patent does not disclose an alternate day dosing. However, it does show that a daily dosage is possible, as a single dosage or as divided and administered in a multiple daily dose regimen. The reference also teaches a staggered

regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc., it would have been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS.

5. Claims 1-18 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382) in view of Shibutani et al. (Iyakuhin Kenkyu, vol. 18(4), pp. 571-82, 1987) and further in view of Sobel (abstract of WO 9420122 or US Patent 5624895).

The disclosure for the patent is as discussed above. The whole range of dosages claimed by the instant invention is not shown. However, the Shibutani abstract indicates that IFN toxicity studies with rats showed that it was tolerated well. Therefore it would have been obvious to one of ordinary skill in the art to administer dosages higher than that shown in the patent with the reasonable expectation that such doses would not produce toxicity side-effects in humans. It would also have been obvious to employ such an alternate day dose regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc. Note that although Cummins discloses interferon for autoimmune diseases which includes the diabetes claimed herein, the reference does not expressly state that the disease

condition is diabetes. However Sobel shows the use interferon for diabetes and that diabetes was known in the art as an autoimmune disease at the time the invention was made. See col. 8, line 63 to col. 9, line 5 and claims 11-12 and 18.

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 1-7 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-7 of copending application Serial No. 08/631470. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

8. Claims 1-18 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-18 of copending application Serial No. 08/844731. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

9. Claims 8-18 are provisionally rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claims 1-18 of copending application Serial No. 08/631470 in view of the abstracts of WO 94/20122, Gross et al. and Giron et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of these claims would have been obvious in view of the abstracts that show that it was already known in the art at the time the invention was made that interferon prevented the onset of diabetes. [Filing date accorded to the claims 8, 12 and 16 reciting diabetes mellitus (prevention, etc.)is 4/15/96].

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

(13) Response to argument.

On page 9 of the brief, appellant has criticized the Cummins reference for showing only one anecdotal report and being "extremely limited" (see declaration submitted). He argues that "this limited clinical data" cannot be considered enabling and therefore should be held "incredible" and therefore non-anticipatory. See page 10 of the brief. Enablement requires that the specification teach

those in the art to make and use the invention without "undue experimentation". *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 140, 1404 (Fed. Cir. 1988). The specification and data therein is considered to be adequate to provide the skilled worker enough to practice the invention without "undue experimentation". A patent cannot be called "non-enabling" because appellant has produced data from 27 patients and 18 controls versus the one example in the patent used. See MPEP §2164.02.

As for amounts discussed at page 17 of the Brief, the claims rejected under 35 USC 102 do not contain the limitation that appellant has based his arguments on (SEE page 7 of the Brief) and as for claim 10 or 14 note that the claim is rendered obvious by Cummins Jr. showing 5 I.U./kg which overlaps with the end point of the claimed range.

Appellant's discussion of Cummins' mode of administration at pages 14-16 of the response is also not persuasive. There is nothing clearly distinguishable between "orally administering...such that the ...interferon is ingested after oral administration" (see claim 1) and Cummins' mode. Appellant has argued at page 15 that in his specification the interferon was fed through a needle inserted into the stomach and there was no oral or pharyngeal contact. There are no such limitations in the claims, however, and the relevance of this argument in view of the instantly claimed limitations and claim recitation is not clear. Appellant cannot rely on the specification to impart to the claims limitations not recited therein. Such a reliance is ineffective to define over the prior art. *In re Lundberg,* 244 F2d 543, 113 USPQ 530 (CCPA 1957), *In re Winkhaus,* 188 USPQ 129 (CCPA 1975). See also *In re Hyson,* 172 USPQ 399, *In re Tiffin,* 171 USPQ 294, *In re Lindner,* 173

USPQ 356: It is well established that the objective evidence of nonobviousness must be commensurate in scope with the claims.

Appellant also argues that there was only "brief" exposure of interferon to the oral mucosa in his method. Pages 13-14 of the Brief. The claims herein do not recite anything to this end and there is no recitation or disclosure to show such a "brief" exposure only. Appellant states on page 14, last 2 sentences that the claims state that the interferon is to be ingested upon oral administration and that the interferon is only in contact with the oral mucosa during the swallowing process, which takes a fairly brief period of time. It is obvious to the artisan from the reference that even in Cummin's mode a small or considerable amount of interferon will be eventually ingested as a normal course of events. The feature of mode of administration urged by appellant as distinguishing enough to be the basis of patentability, is not clear and convincing or of patentable moment, based on the disclosure and claim language.

Appellant's pointing out col. 5, lines 50-55 (see page 19 of the Brief) of Cummins is also unpersuasive. The patent clearly teaches "Daily dosage of interferon....as a single dosage". Appellant argues that although the reference teaches that a regimen of 1-3 days per week or month is discussed, that this is only disclosed as a less preferred embodiment (page 20 of the Brief). Nowhere in any statute is there a requirement that only the preferred embodiment of the reference should be considered a teaching and the rest of the reference be ignored. See *In re Uhlig*, 153 USPQ 460, *In re Mills*, 176 USPQ 196 (CCPA 1972)

Both the traversal of the rejection over claim 5 and

the declaration have been carefully reviewed and considered and the above discussions apply here too.

Appellant's traversal of the rejection of claims 1-18 at page 20 is also in error. Test for combining references is not what individual references themselves suggest but what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1970). Appellant has improperly criticized the references individually where the rejection is based upon the combined teachings of the references. *In re Merck., Inc.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Unobviousness cannot be established by attacking references taken individually when rejection is based on a combination of references. *Ex parte Campbell* 172 USPQ 91 (BPA&I 1971). Note that Shibutani's abstract is used to show toxicity studies only and the motivation it provides to the artisan to do what appellant has done. Sobel shows the use interferon for diabetes and that diabetes was known in the art as an autoimmune disease at the time the invention was made. Similarly, Gross et al and Giron et al references were used only to show that the art was well aware that interferon could be administered to diabetic subjects without side-effects due to toxicity and that interferon prevented diabetes. Such secondary references provide motivation when taken together with Cummins Jr.

Appellant's response to the double patenting and obviousness type double patenting rejections have been noted at pages 5 and 26 of the Brief and those rejections are being maintained as proper and valid. Appellant's response to the Sequence listing requirement has been noted, although

it is recognized that this is not appealable subject matter. The sequence listing has been approved and entered.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

C. Sayala
Art Unit 1761
(703) 308-3035

CHHAYA D. SAYALA
PRIMARY EXAMINER
GROUP 1760

Benjamin Aaron Adler
McGregor & Adler, LLP
8011 Candle Lane
Houston, Texas 77071
(713) 777-2321